CT Corporation

Service of Process Transmittal

09/03/2021
CT Log Number 540188922

TO: Carol Purcell
Endo Pharmaceuticals Inc.
1400 Atwater Dr
Malvern, PA 19355-8701

RE: **Process Served in Delaware**

FOR: Astora Women's Health, LLC (Domestic State: DE)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION:	Re: Gloria Leticia Jasso // To: Astora Women's Health, LLC
DOCUMENT(S) SERVED:	Citation, Return, Original Petition, Certificate
COURT/AGENCY:	206th Judicial District Court of Hidalgo County, TX Case # C345221D
NATURE OF ACTION:	Product Liability Litigation - Personal Injury - MiniArc
ON WHOM PROCESS WAS SERVED:	The Corporation Trust Company, Wilmington, DE
DATE AND HOUR OF SERVICE:	By Process Server on 09/03/2021 at 11:56
JURISDICTION SERVED :	Delaware
APPEARANCE OR ANSWER DUE:	On or before 10:00 o'clock a.m. on the Monday next after the expiration of 20 days after the date of service (Document(s) may contain additional answer dates)
ATTORNEY(S) / SENDER(S):	Danae N. Benton FEARS NACHAWATI LAW FIRM, PLLC 5473 Blair Road Dallas, TX 75231 214-890-0711
REMARKS:	Received for AMERICAN MEDICAL SYSTEMS, INC. converted to AMERICAN MEDICAL SYSTEMS, LLC and forwarded to ASTORA WOMEN'S HEALTH, LLC based upon prior mergers
ACTION ITEMS:	CT has retained the current log, Retain Date: 09/03/2021, Expected Purge Date: 09/08/2021 Image SOP Email Notification, Jobina Jones-McDonnell jones.jobina@endo.com Email Notification, Helen Howlett howlett.helen@endo.com Email Notification, Gary Cennerazzo gary.cennerazzo@parpharm.com Email Notification, Carolyn Hazard hazard.carrie@endo.com Email Notification, Par Notice Dept Par.noticeDept@parpharm.com

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RE: **Process Served in Delaware**

FOR: Astora Women's Health, LLC (Domestic State: DE)

Email Notification, Carol Purcell Purcell.Carol@endo.com

Email Notification, Sandra DiIorio DiIorio.Sandra@endo.com

Email Notification, Julianne Decker julianne.decker@parpharm.com

Email Notification, Bethann Miles miles.bethann@endo.com

Email Notification, Jacqueline Gorbey gorbey.jacqueline@endo.com

Email Notification, Stephanie Chadick chadick.stephanie@endo.com

Email Notification, Lance Arnott sopverification@wolterskluwer.com

REGISTERED AGENT ADDRESS:

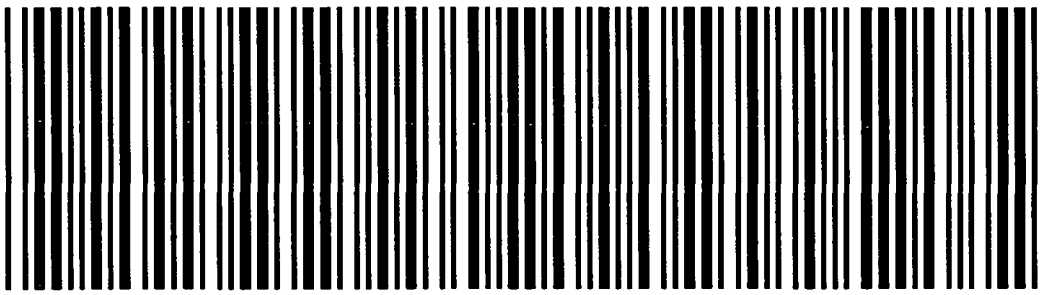
The Corporation Trust Company
1209 Orange Street
Wilmington, DE 19801

866-401-8252
EastTeam2@wolterskluwer.com

Wolters Kluwer

PROCESS SERVER DELIVERY DETAILS

Date:	Fri, Sep 3, 2021
Server Name:	Kevin Dunn
Entity Served	AMERICAN MEDICAL SYSTEMS, INC.
Case Number	C-3452-21-D
Jurisdiction	DE



C-3452-21-D
206TH DISTRICT COURT, HIDALGO COUNTY, TEXAS

CITATION
THE STATE OF TEXAS

NOTICE TO DEFENDANT: You have been sued. You may employ an attorney. If you or your attorney do not file a written answer with the clerk who issued this citation by 10:00 a.m. on the Monday next following the expiration of twenty (20) days after you were served with this citation and petition, a default judgment may be taken against you. In addition to filing a written answer with the clerk, you may be required to make initial disclosures to the other parties of this suit. These disclosures generally must be made no later than 30 days after you file your answer with the clerk. Find out more at TexasLawHelp.org.

American Medical Systems, Inc.
Registered Agent: Corporation Trust Company
1209 N Orange street
Wilmington DE 19801

You are hereby commanded to appear by filing a written answer to the **PLAINTIFF'S ORIGINAL PETITION AND JURY DEMAND** on or before 10:00 o'clock a.m. on the Monday next after the expiration of twenty (20) days after the date of service hereof, before the **Honorable Rose G. Reyna, 206th District Court** of Hidalgo County, Texas at the Courthouse at 100 North Closner, Edinburg, Texas 78539.

Said petition was filed on this the 26th day of August, 2021 and a copy of same accompanies this citation. The file number and style of said suit being C-3452-21-D, **GLORIA LETICIA JASSO VS. AMERICAN MEDICAL SYSTEMS, INC.**

Said Petition was filed in said court by Attorney DANAE N. BENTON, 5473 BLAIR RD DALLAS TX 75231.

The nature of the demand is fully shown by a true and correct copy of the petition accompanying this citation and made a part hereof.

The officer executing this writ shall promptly serve the same according to requirements of law, and the mandates thereof, and make due return as the law directs.

ISSUED AND GIVEN UNDER MY HAND AND SEAL of said Court at Edinburg, Texas on this the 30th day of August, 2021.

LAURA HINOJOSA, DISTRICT CLERK
100 N. CLOSNER, EDINBURG, TEXAS
HIDALGO COUNTY, TEXAS

CINDY LOPEZ, DEPUTY CLERK

DISTRICT COURT, HIDALGO COUNTY

C-3452-21-D
OFFICER'S RETURN

Came to hand on _____ of _____, 202____ at _____ o'clock ____.m. and executed in _____ County, Texas by delivering to each of the within named Defendant in person, a true copy of this citation, upon which I endorsed the date of delivery to said Defendant together with the accompanying copy of the _____ (petition) at the following times and places, to-wit:

NAME	DATE	TIME	PLACE

And not executed as to the defendant, _____ the diligence used in finding said defendant, being: _____ and the cause of failure to execute this process is: _____ and the information received as to the whereabouts of said defendant, being: _____. I actually and necessarily traveled _____ miles in the service of this citation, in addition to any other mileage I may have traveled in the service of other process in the same case during the same trip.

Fees: serving ... copy(s) $_____
miles .....$_____

_____
DEPUTY

COMPLETE IF YOU ARE PERSON OTHER THAN A SHERIFF, CONSTABLE OR CLERK OF THE COURT

In accordance to Rule 107, the officer or authorized person who serves or attempts to serve a citation must sign the return. If the return is signed by a person other than a sheriff, constable or the clerk of the court, the return must either be verified or be signed under the penalty of perjury. A return signed under penalty of perjury must contain the statement below in substantially the following form:

"My name is _____, my date of birth is _____ and the address is _____,and I declare under penalty of perjury that the foregoing is true and correct.

EXECUTED in _____County, State of Texas, on the _____ day of _____, 202___.

_____
Declarant"

_____
If Certified by the Supreme Court of Texas
Date of Expiration / PSC Number

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Hidalgo County District Clerks
Reviewed By: Armando Cantu

CAUSE NO. C-3452-21-D

GLORIA LETICIA JASSO,	§	**IN THE DISTRICT COURT**
Plaintiff,	§	
vs.	§	**_____ JUDICIAL DISTRICT**
AMERICAN MEDICAL SYSTEMS, INC.,	§	
Defendant.	§	**HIDALGO COUNTY, TEXAS**

PLAINTIFF'S ORIGINAL PETITION AND JURY DEMAND

Plaintiff, Gloria Leticia Jasso, by and through her undersigned counsel, files this Petition and Jury Demand against Defendant American Medical Systems, Inc., and alleges as follows:

DISCOVERY

1. Pursuant to Rule 190 et seq of the Texas Rules of Civil Procedure, Plaintiff requests a Level III discovery control plan.

PLAINTIFF

2. Plaintiff Gloria Leticia Jasso ("Plaintiff"), at all times relevant to this action is a citizen of and resides in and continues to reside in Weslaco, Texas, which is located in Hidalgo County Texas. Plaintiff was injured as a result of having one of Defendant American Medical Systems, Inc.'s ("Defendant") Pelvic Mesh Products ("Pelvic Mesh Products" or "Products"), the MiniArc Precise Single Incision Sling System ("MiniArc"), implanted into her vaginal area to treat stress urinary incontinence ("SUI") and therefore seeks damages for pain and suffering, ascertainable economic losses, attorneys' fees, reimbursement of the cost of the mesh,

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reimbursement for all past health and medical care costs related to the implantation of Defendant's MiniArc, and subsequent revision/removal surgery.

DEFENDANT

3. American Medical Systems, Inc. ("AMS") is a Delaware Corporation and may be served pursuant to 10 Del. C. §3111 by serving its registered agent, Corporation Trust Company, at 1209 N. Orange Street, Wilmington, Delaware 19801.

4. At all relevant times material to this action, Defendant has designed, patented, manufactured, labeled, marketed, sold, and distributed a line of Pelvic Mesh Products, including the MiniArc implanted in Plaintiff. These products were designed primarily for the purpose of treating stress urinary incontinence and pelvic organ prolapse. These products share common design elements and common defects. Moreover, each of these products, including the MiniArc, were cleared for sale in the U.S. after the Defendant made assertions to the Food and Drug Administration of "Substantial Equivalence" under Section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety or efficacy.

JURISDICTION AND VENUE

5. At all relevant times, Defendant transacted, solicited, and conducted business in Hidalgo County, in the State of Texas, and derived substantial revenue from such business.

6. At all relevant times, Defendant expected or should have expected that its acts would have consequences within the United States of America and the State of Texas.

7. Venue is proper in Hidalgo County, Texas, because all the events and omissions giving rise to Plaintiff's claims occurred in Hidalgo County, Texas.[1]

[1](a) Except as otherwise provided by this subchapter or Subchapter B or C,1 all lawsuits shall be brought: (1) in the county in which all or a substantial part of the events or omissions giving rise to the claim occurred; (2) in the county of defendant's residence at the time the cause of action accrued if defendant is a natural person; (3) in the county of the defendant's principal office in this state, if the defendant is not a natural person; or (4) if Subdivisions (1), (2), and (3) do not apply, in the county in which the plaintiff resided at the time of the accrual of the cause of action. Tex. Civ. Prac. & Rem. Code Ann. § 15.002

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8. This Court has original jurisdiction over this action because the amount in controversy exceeds $500.[2] Although Plaintiff has confidence that the Jury will award a fair and just amount of damages in this matter, Plaintiff is required to plead a specific amount of damages or Defendant may seek Court intervention. Accordingly, although Plaintiff leaves the amount of damages to the Jury, Plaintiff would show the Court and Jury that due to the actions of Defendant, Plaintiff is entitled to monetary relief of over $250,000.00 but not more than $1,000,000.00, including damages of any kind, penalties, costs, expenses, pre-judgement interest, and attorney's fees.

9. The Court has personal jurisdiction over Defendant because Defendant committed a tortious act within the State of Texas.[3]

10. Defendant marketed, advertised, and distributed its Pelvic Mesh Products in the State of Texas. The Court has personal jurisdiction over Defendant because Defendant transacted business within the State of Texas.

FACTUAL BACKGROUND

11. Plaintiff Gloria Leticia Jasso was diagnosed with stress urinary incontinence and menorrhagia in 2010. Her physician, Dr. Annabelle Lopez, recommended implantation of the MiniArc as the appropriate course of treatment to remedy Plaintiff's stress urinary incontinence and menorrhagia. Dr. Annabelle Lopez surgically implanted the MiniArc into Plaintiff's vaginal area on November 23, 2010, at KNAPP Medical Center, located in Weslaco, Texas. The MiniArc in question is defined by Defendant as Model number 720191-01, Lot number 680212074. Shortly after the procedure, Plaintiff began suffering from dysuria, nocturia, recurrent pelvic and perineal

[2] "(b) A district court has original jurisdiction of a civil matter in which the amount in controversy is more than $500, exclusive of interest." Tex. Gov't Code Ann. § 24.007.

[3] "In addition to other acts that may constitute doing business, a nonresident does business in this state if the nonresident...(2) commits a tort in whole or in part in this state..." Tex. Civ. Prac. & Rem. Code Ann. § 17.042(2).

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pain, recurrent abdominal pain, urinary tract infections, recurrent incontinence, rectal bleeding, and acute cystitis.

12. On September 5, 2019, Dr. Henry Evangelista Ruiz performed revision surgery on Plaintiff to remove the MiniArc from Plaintiff's vaginal area. Dr. Ruiz noted that Plaintiff had, in addition to the above-referenced conditions/symptoms, developed dyspareunia and vaginal discharge. Dr. Ruiz also found that the Miniarc was eroding into Plaintiff's anterior vaginal wall. Plaintiff suffered through the pain of this additional surgery and had to assume the risk of complications associated with general anesthesia surgery.

13. Pelvic Mesh Products are used to treat women with pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). Pelvic organ prolapse occurs when a pelvic organ, such as the bladder, drops ("prolapses") from its normal position and pushes against the walls of the vagina. Prolapse can happen if the muscles that hold the pelvic organs in place become weak or stretched from childbirth or surgery. More than one pelvic organ can prolapse at the same time. Organs that can be involved in a pelvic organ prolapse include the bladder, the uterus, the bowel and the rectum. Stress urinary incontinence is a type of incontinence characterized by leakage of urine during moments of physical stress. MiniArc is marketed to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma, and minimal pain while correcting urinary incontinence.

14. Defendant's MiniArc contains monofilament polypropylene mesh and/or polypropylene.

15. Despite Defendant's claims that polypropylene is inert, the scientific evidence shows that this material as implanted in Plaintiff in the MiniArc is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population

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implanted with Defendant's Pelvic Mesh Products, including the MiniArc implanted in Plaintiff. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. Furthermore, Defendant's MiniArc causes hyper-inflammatory responses leading to problems, including chronic pain and fibrotic reactions. Defendant's MiniArc disintegrates after implantation in the female pelvis. This product causes adverse tissue reaction and is causally related to infection. When mesh is inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

16. Defendant sought and obtained FDA clearance to market the MiniArc under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to the Products, including the MiniArc.

17. On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 reports of complications (otherwise known as "adverse events") that had been reported over a three-year period relating to pelvic mesh products.

18. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that the Defendant is the manufacturer of the products noted in the notification. In 2008, the FDA described the complications associated with pelvic mesh products as "rare."

19. On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are not

rare." The MiniArc is made using the same polypropylene mesh used in products designed for POP repair.

20. The FDA Safety Communication also stated, "Mesh contraction (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA . . . Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." The MiniArc is made using the same polypropylene mesh used in products designed for POP repair.

21. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks.

22. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk." The MiniArc is made using the same polypropylene mesh used in products designed for POP repair.

23. In July 2011 the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the "White Paper"). In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh." The MiniArc is made using the same polypropylene mesh used in products designed for POP repair.

24. The FDA White Paper summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using

transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk." The MiniArc is made using the same polypropylene mesh used in products designed for POP repair.

25. The FDA White Paper further stated that "these products are associated with serious adverse events . . . Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair."

26. In its White Paper, the FDA advises doctors to, inter alia, "[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications." The FDA concludes its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse." The MiniArc is made using the same polypropylene mesh used in products designed for POP repair.

27. At the time Defendant began marketing each of its Pelvic Mesh Products, including specifically the product at issue in this case—the MiniArc—Defendant was aware that its Pelvic Mesh Products were associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011 Safety Communication.

28. The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011, was known or knowable to Defendant and was not disclosed in oral or written communications, direct to consumer advertising in the form of patient brochures, instructions of use or labeling.

29. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS")

also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh . . . Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

30. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk." The MiniArc is made using the same polypropylene mesh used in products designed for POP repair.

31. The injuries sustained by the female Plaintiff as will be more fully set forth in the Plaintiff's Fact Sheet to be served in this civil action are consistent with the complications identified in the ACOG/AUGS Joint Committee Opinion.

32. Defendant knew or should have known about the Products' risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

33. Defendant knew or should have known that the MiniArc unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

34. The scientific evidence shows that the material from which Defendant's Pelvic Mesh Products, such as the MiniArc, are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with Defendant's Pelvic Mesh Products, such as the AMS MiniArc, including the Plaintiff.

35. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by the Plaintiff.

36. The FDA defines both "degradation" and "fragmentation" as "device problems" to

which the FDA assigns a specific "device problem code." "Material fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." The MiniArc is unreasonably susceptible to degradation and fragmentation inside the body.

37. The MiniArc is unreasonably susceptible to shrinkage and contraction inside the body.

38. The MiniArc is unreasonably susceptible to "creep" or gradual elongation and deformation when subject to prolonged tension inside the body.

39. The MiniArc has been and continues to be marketed to the medical community and to patients as a safe, effective, reliable, medical device, implanted by safe, effective, and minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of stress urinary incontinence, and other competing products.

40. Defendant omitted the risks, dangers, defects, and disadvantages of the MiniArc, and advertised, promoted, marketed, sold and distributed them as safe medical devices when Defendant knew or should have known that the MiniArc was, and is not safe for its intended purposes, and that the Products would cause, and did cause, serious medical problems, and in some patients, including the Plaintiff, catastrophic injuries.

41. Contrary to Defendant's representations and marketing to the medical community and to the patients themselves, the MiniArc has high rates of failure, injury, and complications, failure to perform as intended, require frequent and often debilitating re-operations, and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff, making them defective under the law.

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42. The specific nature of the MiniArc defects includes, but is not limited to, the following:

a. the use of polypropylene material in the MiniArc and the immune reactions that result from such material, causes adverse reactions and injuries;

b. the design of the MiniArc to be inserted transvaginally, into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the MiniArc, including, but not limited to, their propensity to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the MiniArc, which, when placed in women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

e. the propensity of the MiniArc for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the MiniArc, causing it to be improperly mated to the delicate and sensitive areas of the vagina and pelvis when implanted, causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

g. the propensity of the MiniArc to degrade or fragment over time, which causes a chronic inflammatory and fibrotic reaction, resulting in continuing injury over time;

h. the female body's hyper-inflammatory responses to polypropylene leading to problems including chronic pain and fibrotic reaction;

i. the adverse tissue reactions caused by the polypropylene in the MiniArc, which are causally related to infection, as the polypropylene is a foreign material;

j. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions;

k. the procedure itself, which is part of Defendant's MiniArc, requires the physician to insert the device "blindly" resulting in nerve damage and damage to other internal organs;

l. the design of trocars, part of Defendant's MiniArc, used to insert the Pelvic Mesh Products into the vagina, are defective because the device requires tissue penetration in nerve rich environments which frequently results in the destruction of nerve endings causing pain and other injuries.

43. The MiniArc is also defective due to Defendant's failure to adequately warn or instruct the Plaintiff and/or her health care providers of subjects including, but not limited to, the

following:

a. the MiniArc's propensity to contract, retract, and/or shrink inside the body;

b. the MiniArc's propensity for degradation, fragmentation and/or creep;

c. the MiniArc's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the MiniArc;

f. the risk of chronic infections resulting from the MiniArc;

g. the risk of permanent vaginal or pelvic scarring as a result of the MiniArc;

h. the risk of permanent vaginal shortening resulting from the MiniArc;

i. the risk of recurrent, intractable pelvic pain and other pain resulting from the MiniArc;

j. the need for corrective or revision surgery to adjust or remove the MiniArc;

k. the severity of complications that could arise as a result of implantation of the MiniArc;

l. the hazards associated with the MiniArc;

m. the MiniArc's defects described herein;

n. treatment of stress urinary incontinence with the MiniArc is no more effective than feasible available alternatives;

o. treatment of stress urinary incontinence with the MiniArc exposes patients to greater risk than feasible available alternatives;

p. treatment of stress urinary incontinence with the MiniArc makes future surgical repair more difficult than feasible available alternatives;

q. use of the MiniArc puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

r. removal of the MiniArc due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

s. complete removal of the MiniArc may not be possible and may not result in complete resolution of the complications, including pain.

44. Defendant has underreported information about the propensity of the MiniArc to fail and cause injury and complications and has made unfounded representations regarding the efficacy and safety of the MiniArc through various means and media. Defendant has also

underreported information about the injuries caused by the use of the implantation kits and surgical technique instructions that accompany their Pelvic Mesh Products, such as the MiniArc.

45. Defendant failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the MiniArc.

46. Defendant failed to design and establish a safe, effective procedure for removal of the MiniArc, or to determine if a safe, effective procedure for removal of the MiniArc exists.

47. Feasible and suitable alternatives to the MiniArc existed at all relevant times that do not present the same frequency or severity of risks associated with the MiniArc.

48. The MiniArc was at all times utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use, created the procedures for implanting them, provided the surgical kits for implantation, and provided training for the implanting physician.

49. Defendant provided incomplete and insufficient training and information to physicians regarding the use of the MiniArc and the aftercare of patients implanted with the MiniArc.

50. The MiniArc implanted in the Plaintiff was in the same or substantially similar condition as it was when it left Defendant's possession, and in the condition directed by and expected by Defendant.

51. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with Defendant's MiniArc include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain and

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other debilitating complications.

52. In many cases, including the Plaintiff's, women have been forced to undergo extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

53. The medical and scientific literature studying the effects of Defendant's Pelvic Mesh Products, including the MiniArc implanted in the Plaintiff, examined each of these injuries, conditions, and complications, and reported that they are causally related to the Transvaginal and Pelvic Mesh Products as described in detail above.

54. Removal of contracted, eroded and/or infected mesh can require multiple surgical interventions and results in scarring on fragile compromised pelvic tissue and muscles.

55. At all relevant times herein, Defendant continued to promote the MiniArc as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy.

56. In doing so, Defendant failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the MiniArc.

57. At all relevant times herein, Defendant failed to provide sufficient warnings and instructions that would have put the Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the MiniArc.

58. The MiniArc as designed, manufactured, distributed, sold and/or supplied by Defendant was defective as marketed due to inadequate warnings, instructions, labeling and/or testing in spite of Defendant's knowledge of the Product's lack of safety.

59. As a result of having Defendant's MiniArc implanted in her, and then rremoved,

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the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

CAUSES OF ACTION

COUNT 1: NEGLIGENCE

60. Plaintiff hereby incorporates by reference and reavers each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein.

61. Defendant had a duty to individuals, including the Plaintiff, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the MiniArc.

62. Defendant was negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the MiniArc. Defendant breached their aforementioned duty by:

a. Failing to design the MiniArc so as to avoid an unreasonable risk of harm to women in whom the MiniArc was implanted, including the Plaintiff;

b. Failing to manufacture the MiniArc so as to avoid an unreasonable risk of harm to women in whom the MiniArc was implanted, including the Plaintiff;

c. Failing to use reasonable care in the testing of the MiniArc so as to avoid an unreasonable risk of harm to women in whom the MiniArc was implanted, including the Plaintiff;

d. Failing to use reasonable care in inspecting the MiniArc so as to avoid an unreasonable risk of harm to women in whom the MiniArc was implanted, including Plaintiff;

e. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the MiniArc.

63. The reasons that Defendant's negligence caused the MiniArc to be unreasonably dangerous and defective include, but are not limited to:

a. the use of polypropylene material in the MiniArc and the immune reaction that results from such material, causing adverse reactions and injuries;

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b. the design of the MiniArc to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the MiniArc, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the MiniArc, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the MiniArc for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the MiniArc, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation); and

g. the propensity of the MiniArc for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time; and

h. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturer's instructions.

64. Defendant also negligently failed to warn or instruct the Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. the MiniArc's propensity to contract, retract, and/or shrink inside the body;

b. the MiniArc's propensity for degradation, fragmentation and/or creep;

c. the MiniArc's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the MiniArc;

f. the risk of chronic infections resulting from the MiniArc;

g. the risk of permanent vaginal or pelvic scarring as a result of the MiniArc;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the MiniArc;

i. the need for corrective or revision surgery to adjust or remove the MiniArc;

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j. the severity of complications that could arise as a result of implantation of the MiniArc;

k. the hazards associated with the MiniArc;

l. the MiniArc's defects described herein;

m. treatment of stress urinary incontinence with the MiniArc is no more effective than feasible available alternatives;

n. treatment of stress urinary incontinence with the MiniArc exposes patients to greater risk than feasible available alternatives;

o. treatment of stress urinary incontinence with the MiniArc makes future surgical repair more difficult than feasible available alternatives;

p. use of the MiniArc puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the MiniArc due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the MiniArc may not be possible and may not result in complete resolution of the complications, including pain.

65. As a direct and proximate result of Defendant's negligence, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

66. Defendant's misconduct rises to the level of gross negligence under Texas law as defined by Tex. Civ. Prac. & Rem. Code §41.001(11)[4], as outlined below:

67. Defendant sold its Products to Plaintiff's health care providers and other healthcare providers in the state of implantation, Texas, and throughout the United States without doing adequate testing to ensure that the Products were reasonably safe for implantation in the female pelvic area.

[4]"(11) "Gross negligence" means an act or omission: (A) which when viewed objectively from the standpoint of the actor at the time of its occurrence involves an extreme degree of risk, considering the probability and magnitude of the potential harm to others; and (B) of which the actor has actual, subjective awareness of the risk involved, but nevertheless proceeds with conscious indifference to the rights, safety, or welfare of others." Tex. Civ. Prac. & Rem. Code Ann. § 41.001.

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68. Defendant sold the Products to the Plaintiff's health care providers and other health care providers in the state of Texas and throughout the United States in spite of its knowledge that its Products can shrink, disintegrate and/or degrade inside the body, and cause other problems mentioned throughout this Petition, thereby causing severe and debilitating injuries suffered by the Plaintiff and numerous other women.

69. Defendant ignored reports from patients and health care providers throughout the United States and elsewhere of their MiniArc's failure to perform as intended, which led to the severe and debilitating injuries suffered by the Plaintiff and numerous other women. Rather than doing adequate testing to determine the cause of these injuries, or to rule out the MiniArc's design as the cause of these injuries, Defendant instead chose to continue to market and sell the MiniArc as safe and effective.

70. Defendant knew that their MiniArc was unreasonably dangerous in light of its risks of failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the MiniArc, as well as other severe and personal injuries which were permanent and lasting in nature.

71. Defendant withheld material information from the medical community and the public in general, including the Plaintiff, regarding the safety and efficacy of the MiniArc.

72. Defendant knew and recklessly disregarded the fact that the MiniArc caused debilitating and potentially life altering complications with greater frequency than feasible alternative methods and/or products used to treat and stress urinary incontinence.

73. Defendant misstated and misrepresented data and continues to misrepresent data so as to minimize the perceived risk of injuries caused by the MiniArc.

74. Notwithstanding the foregoing, Defendant continues to aggressively market the

MiniArc to consumers, without disclosing the true risks associated with the MiniArc.

75. Defendant knew of the MiniArc's defective and unreasonably dangerous nature, but continued to manufacture, market, distribute, and sell the MiniArc so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff.

76. Defendant continues to conceal and/or fail to disclose to the public, including the Plaintiff, the serious complications associated with the use of the MiniArc to ensure continued and increased sales of the MiniArc.

77. Defendant's aforementioned conduct illustrates the extreme degree of risk that the implantation of Defendant's MiniArc subjects upon women, such as Plaintiff, even though Defendant knew, at all relevant times, that its MiniArc had a high probability of causing potential harm to women, such as Plaintiff, implanted with its MiniArc.[5]

78. Defendant's awareness of the severe harm that its MiniArc could inflict on women, such as Plaintiff, who were implanted with its MiniArc, demonstrates Defendant's "conscious indifference to the rights, safety, or welfare" of women, such as Plaintiff.[6]

WHEREFORE, said Plaintiff prays for judgement against Defendant.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

79. Plaintiff hereby incorporates by reference and reavers each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein.

80. The Defendant's Pelvic Mesh Products, including the MiniArc, are dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet of perform to the expectations of patients and their health care providers.

[5] Tex. Civ. Prac. & Rem. Code Ann. § 41.001(A).
[6] Tex. Civ. Prac. & Rem. Code Ann. § 41.001(B).

81. Feasible and suitable alternatives to Defendant's Pelvic Mesh Products, such as the MiniArc, have existed at all times relevant that do not present the same frequency or severity of the risks that Defendant's Pelvic Mesh Products, such as the MiniArc, do.

82. As previously stated, the MiniArc's design defects include, but are not limited to:

a. the use of polypropylene material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of MiniArc to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of MiniArc, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the MiniArc, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the MiniArc to "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the MiniArc, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation); and

g. the propensity of the MiniArc for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the propensity of the polypropylene containing MiniArc to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

i. the adverse tissue reactions caused by the polypropylene containing MiniArc, which are causally related to infection;

j. the hardening of the polypropylene containing MiniArc in the body;

k. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the MiniArc is implanted according to the manufacturers' instructions.

83. As a direct and proximate result of the MiniArc's defects as described herein, Plaintiff has experienced significant mental and physical pain and suffering, has sustained

permanent injury, has undergone medical treatment, and will likely undergo future medical treatments and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

84. Defendant is strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product

WHEREFORE, said Plaintiff prays for judgement against Defendant.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

85. Plaintiff hereby incorporates by reference and reavers each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein.

86. Defendant's MiniArc, as implanted into Plaintiff's vaginal area, was not reasonably safe for its intended use and was defective as described herein as a matter of law with respect to its manufacture, in that Defendant's Pelvic Mesh Products, such as the MiniArc, deviated materially from Defendant's design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to women, such as Plaintiff, who were implanted with Defendant's Pelvic Mesh Products, including the MiniArc.

87. As a direct and proximate result of the MiniArc's defects as described herein, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment, and will likely undergo future medical treatments and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

88. Defendant is strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging, and selling its defective Pelvic Mesh Products, such as the MiniArc.

WHEREFORE, said Plaintiff prays for judgement against Defendant.

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COUNT IV: FRAUD BY MISREPRESENTATION

89. Plaintiff hereby incorporates by reference and reavers each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein.

90. On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 reports of complications (otherwise known as "adverse events") that had been reported over a three-year period relating to pelvic mesh products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that the Defendants are the manufacturers of the products noted in the notification. In 2008, the FDA described the complications associated with pelvic mesh products as "rare."

91. On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are not rare." The MiniArc is made using the same polypropylene mesh used in products designed for POP repair.

92. "To state a claim of fraud by misrepresentation under Texas law, a plaintiff must sufficiently allege (1) a [material] misrepresentation that (2) the speaker knew to be false or made recklessly (3) with the intention to induce the plaintiff's reliance, followed by (4) actual and justifiable reliance (5) causing injury."[7]

93. Defendant's misconduct constitutes fraud by misrepresentation under Texas law due to the following material misrepresentations made by Defendant knowingly and recklessly:

a. At all times prior to the October 20, 2008, Public Health Notification to the present, it was known or knowable to Defendant that its Pelvic Mesh Products caused large numbers of complications that were not rare. Moreover, it was known or knowable to Defendant that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with

[7] *Butler v. Juno Therapeutics, Inc.*, No. CV H-18-898, 2019 WL 2568477, at *26 (S.D. Tex. June 21, 2019).

these devices;

b. It was known or knowable to Defendant that the safety and efficacy of its Pelvic Mesh Products, including the MiniArc, had not been proven with respect to, among other things, the product, its components, its performance and its method of implantation;

c. Defendant continued to represent that its Pelvic Mesh Products, including the MiniArc, were safe and effective, despite the fact that it was known or knowable to Defendant that there was no evidence that its Pelvic Mesh Products, including the MiniArc, were safe and effective and, in fact, the evidence that was known or knowable to Defendant was that its Pelvic Mesh Products, including the MiniArc, were not safe and effective; and

d. Defendant continued to conceal and/or fail to disclose to the general public, the medical community, and women, including Plaintiff, who were, or were going to be, implanted with its Pelvic Mesh Products, including the MiniArc, the serious complications associated with the use of Defendant's Pelvic Mesh Products, including the MiniArc, in order to ensure continued and increased sales of its Pelvic Mesh Products, such as the MiniArc.

94. As a direct and proximate result of the aforementioned misrepresentations made by Defendant, Plaintiff has suffered significant mental and physical pain and suffering, and sustained permanent injury.

WHEREFORE, said Plaintiff prays for judgement against Defendant.

COUNT V: TEXAS DECEPTIVE TRADE PRACTICES AND CONSUMER PROTECTION

95. Plaintiff hereby incorporates by reference and reavers each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein.

96. Defendant's misconduct constitutes multiple violations of Deceptive Trade Practices and Consumer Protection laws, codified in the Tex. Bus. & Com. Code Ann. § 17.46, which states, in part, "False, misleading, or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful and are subject to action by the consumer protection division..." Such acts or practices include, but are not limited to, "representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or

model, if they are of another"[8], and "failing to disclose information concerning goods or services which was known at the time of the transaction if such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed."[9]

97. The MiniArc has been and continues to be marketed to the medical community and to patients as a safe, effective, reliable, medical device, implanted by safe, effective, and minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatment of stress urinary incontinence, and other competing products.

98. At the time Defendant began marketing each of its Pelvic Mesh Products, including the product at issue in this case—the MiniArc—Defendant was aware that its Pelvic Mesh Products were associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011, Safety Communication.

99. The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011, was known or knowable to Defendant and was not disclosed in oral or written communications, direct to consumer advertising in the form of patient brochures, instructions of use or labeling.

100. Defendant continued to conceal and/or fail to disclose to the general public, the medical community, and women, including Plaintiff, who were, or were going to be, implanted with its Pelvic Mesh Products, including the MiniArc, the serious complications associated with the use of Defendant's Pelvic Mesh Products, including the MiniArc, in order to ensure continued and increased sales of its Pelvic Mesh Products, such as the MiniArc.

101. As a direct and proximate result of the above actions taken by the Defendant,

[8] Tex. Bus. & Com. Code Ann. § 17.46(b)(7).
[9] Tex. Bus. & Com. Code Ann. § 17.46(b)(25).

Plaintiff has suffered significant mental and physical pain and suffering and sustained permanent injury.

WHEREFORE, said Plaintiff prays for judgement against Defendant.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

102. Plaintiff hereby incorporates by reference and reavers each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein.

103. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

104. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute until Plaintiff knew, or through the exercise of reasonable case and diligence should have known, of facts indicating her injury, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

105. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with Plaintiff's medical providers, the nature of the injuries and damages, and their relation to the MiniArc, it was not discovered, and through reasonable case and diligence could not have been discovered, until a date within the applicable statute of limitations for Plaintiff's claims. Therefore, under appropriate application of the discovery rule, the action was filed well within the applicable statutory limitations period.

106. The running of the statute of limitations should be tolled due to equitable tolling. Defendant should be estopped from asserting a limitations defense due to its fraudulent concealment, through misrepresentations and omissions, from Plaintiff and Plaintiff's physicians of the true risks associated with the MiniArc. As a result of Defendant's fraudulent concealment,

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Plaintiff and her physicians were unaware, and could not have known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks alleged in this Petition, and that those risks were the direct and proximate result of Defendant's wrongful acts and omissions.

PRAYER FOR RELIEF

107. WHEREFORE, Plaintiff demands judgment against Defendant and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

a. Compensatory damages to Plaintiff for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, mental anguish, health and medical care costs, together with interest and costs as provided by law;

b. Unjust enrichment;

c. Restitution and disgorgement of profits;

d. Reasonable attorneys' fees;

e. The cost of these proceedings;

f. All ascertainable economic damages;

g. Punitive damages (if finding of gross negligence is upheld by the court); and

h. Such other and further relief as this Court deems just and proper.

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JURY TRIAL DEMAND

Plaintiff demands a trial by jury on all of the triable issues within this Petition.

Dated: August 26, 2021

FEARS NACHAWATI LAW FIRM, PLLC

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Hannah Aiken on behalf of Danae Benton
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Status as of 8/26/2021 10:59 AM CST

Associated Case Party: GloriaLeticiaJasso

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